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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

NAZARENKO *et al.*

Appl. No. 10/026,952

Filed: December 27, 2001

For: **Primers and Methods for the Detection and Discrimination of Nucleic Acids**

Confirmation No.: 7365

Art Unit: 1623

Examiner: To be assigned

Atty. Docket: 0942.4980006/RWE/AGU

Preliminary Amendment

Commissioner for Patents
Washington, D.C. 20231

Sir:

In advance of prosecution in the above identified matter and in compliance with the Response to Request for Corrected Official Filing Receipt, mailed on March 13, 2002, please amend the application as follows:

This Amendment is provided in the following format:

- (A) A clean version of each replacement paragraph/section/claim along with clear instructions for entry;
- (B) Starting on a separate page, appropriate remarks and arguments. *See* 37 C.F.R. § 1.121 and MPEP 714; and
- (C) Starting on a separate page, a marked-up version entitled: “Version with markings to show changes made.”

In the Claims:

Please substitute the following claims 63 and 65-67 for the pending claims 63 and 65-67:

63. (Once Amended) A method for the quantitation or detection of one or more nucleic acid molecules in a sample during nucleic acid synthesis comprising:

mixing one or more nucleic acid templates with one or more oligonucleotides, wherein said oligonucleotides contain an oligonucleotide of claims 42 or 51;

incubating said mixture under conditions sufficient to synthesize one or more nucleic acid molecules complementary to all or a portion of said templates, said synthesized nucleic acid molecule comprising said oligonucleotides; and

detecting the presence or absence or quantifying the amount of said synthesized nucleic acid molecules by measuring the amount of nucleic acid molecules synthesized in said sample.

65. (Once Amended) A method of determining the presence of one or more particular nucleotides at a specific position or positions in a target nucleic acid molecule, comprising:

contacting at least one target nucleic acid molecule having one or more nucleotides of interest at a specific position or positions on a target nucleic acid molecule with at least one oligonucleotide, wherein at least a portion of the oligonucleotide is capable of forming base pairs or hybridizing with at least a portion of the target nucleic acid molecule and wherein the oligonucleotide comprises an oligonucleotide of claims 42 or 51; and

incubating the oligonucleotide and the target nucleic acid molecule under conditions sufficient to cause extension of the oligonucleotide when the 3'-most nucleotide or

nucleotides of the oligonucleotide base pair with the nucleotide or nucleotides at the specific position or positions of the target nucleic acid molecule, wherein the production of an extension product indicates the presence of the particular nucleotide at the specific position.

66. (Once Amended) A method of determining the absence of one or more particular nucleotides at a specific position or positions in a target nucleic acid molecule, comprising:

contacting at least one target nucleic acid molecule having one or more nucleotides of interest at a specific position or positions on the target nucleic acid molecule with at least one oligonucleotide, wherein at least one portion of the oligonucleotide is capable of forming base pairs or hybridizing with at least a portion of the target nucleic acid molecule and wherein the oligonucleotide comprises an oligonucleotide of claims 42 or 51; and

incubating the oligonucleotide and target nucleic acid molecule under conditions sufficient to inhibit or prevent extension of the oligonucleotide when the 3'-most nucleotide or nucleotides of the oligonucleotide does not substantially base pair with the nucleotide or nucleotides of the specific position or positions of the target nucleic acid molecule, wherein the lack of or reduced production of an extension product indicates the absence of the particular nucleotide at the specific position.

67. (Once Amended) A method of determining the presence or absence of one or more particular nucleotides at a specific position or positions in a target nucleic acid molecule, comprising:

contacting at least first oligonucleotide with at least one target nucleic acid molecule under conditions sufficient to cause extension of the first oligonucleotide when the 3'-most nucleotide or nucleotides of the oligonucleotide base pairs with the nucleotide or nucleotides at the specific position or positions of the target nucleic acid molecule;

contacting at least a second oligonucleotide with at least one target nucleic acid molecule under conditions sufficient to inhibit or prevent extension of the oligonucleotide when the 3'-most nucleotide or nucleotides of the oligonucleotide do not substantially base pair with the nucleotide or nucleotides at the specific position or positions of the target nucleic acid molecule; and

comparing the level of extension or the amount of extension product accomplished with the first oligonucleotide compared to the second oligonucleotide, wherein said first and/or second oligonucleotide comprises an oligonucleotide of claims 42 or 51.

In the Specification:

Please substitute pending paragraph [0001] with the following paragraph [0001]:

The present application claims the benefit of both U.S. Provisional Application 60/330,468, filed October 23, 2001, and U.S. Application No. 09/748,146, filed December 27, 2000, which are incorporated herein by reference in their entirety.

Remarks

The foregoing amendment to the specification is sought to provide proper cross-reference to the priority information for this application and to correct a dependency error in the claims. Therefore, these amendments do not add new matter. Entry of this amendment is therefore respectfully requested.

None of the foregoing amendment adds new matter. Accordingly, Applicants respectfully request that the foregoing amendment be entered and considered.

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Summary

It is respectfully believed that this application is now in condition for examination.
Early notice to this effect is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

Date: April 30, 2002

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Please substitute the following claims 63 and 65-67 for the pending claims 63 and 65-67:

incubating said mixture under conditions sufficient to synthesize one or more nucleic acid molecules complementary to all or a portion of said templates, said synthesized nucleic acid molecule comprising said oligonucleotides; and

detecting the presence or absence or quantifying the amount of said synthesized nucleic acid molecules by measuring the amount of nucleic acid molecules synthesized in said sample.

65. (Once Amended) A method of determining the presence of one or more particular nucleotides at a specific position or positions in a target nucleic acid molecule, comprising:

contacting at least one target nucleic acid molecule having one or more nucleotides of interest at a specific position or positions on a target nucleic acid molecule with at least one oligonucleotide, wherein at least a portion of the oligonucleotide is capable of forming base pairs or hybridizing with at least a portion of the target nucleic acid molecule and wherein the oligonucleotide comprises an oligonucleotide of claims [41] 42 or 51; and

incubating the oligonucleotide and the target nucleic acid molecule under conditions sufficient to cause extension of the oligonucleotide when the 3'-most nucleotide or nucleotides of the oligonucleotide base pair with the nucleotide or nucleotides at the specific position or positions of the target nucleic acid molecule, wherein the production of an extension product indicates the presence of the particular nucleotide at the specific position.

66. (Once Amended) A method of determining the absence of one or more particular nucleotides at a specific position or positions in a target nucleic acid molecule, comprising:

contacting at least one target nucleic acid molecule having one or more nucleotides of interest at a specific position or positions on the target nucleic acid molecule with at least one oligonucleotide, wherein at least one portion of the oligonucleotide is capable of forming base pairs or hybridizing with at least a portion of the target nucleic acid molecule and wherein the oligonucleotide comprises an oligonucleotide of claims [41] 42 or 51; and

incubating the oligonucleotide and target nucleic acid molecule under conditions sufficient to inhibit or prevent extension of the oligonucleotide when the 3'-most nucleotide or nucleotides of the oligonucleotide does not substantially base pair with the nucleotide or nucleotides of the specific position or positions of the target nucleic acid molecule, wherein the lack of or reduced production of an extension product indicates the absence of the particular nucleotide at the specific position.

67. (Once Amended) A method of determining the presence or absence of one or more particular nucleotides at a specific position or positions in a target nucleic acid molecule, comprising:

contacting at least first oligonucleotide with at least one target nucleic acid molecule under conditions sufficient to cause extension of the first oligonucleotide when the 3'-most nucleotide or nucleotides of the oligonucleotide base pairs with the nucleotide or nucleotides at the specific position or positions of the target nucleic acid molecule;

contacting at least a second oligonucleotide with at least one target nucleic acid molecule under conditions sufficient to inhibit or prevent extension of the oligonucleotide when the 3'-most nucleotide or nucleotides of the oligonucleotide do not substantially base pair with the nucleotide or nucleotides at the specific position or positions of the target nucleic acid molecule; and

comparing the level of extension or the amount of extension product accomplished with the first oligonucleotide compared to the second oligonucleotide, wherein said first and/or second oligonucleotide comprises an oligonucleotide of claims [41] 42 or 51.

In the Specification:

Please substitute pending paragraph [0001] with the following paragraph [0001]:

The present application claims the benefit of both U.S. Provisional Patent Application No. 60/330,468, filed October 23, 2001, [which is related to] and U.S. Application No. 09/748,146, filed December 27, 2000, [which is a continuation-in-part of U.S. Application No. 09/599,594, filed June 22, 2000, which claims the benefit of U.S. Provisional Patent Application Nos. 60/139,890, filed June 22, 1999, and 60/175,959, filed January 13, 2000,] which are incorporated herein by reference in their entirety.



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Letter to PTO Draftsman: Submission of Formal Drawings

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith are 60 sheets of formal drawings with Figures 1A-1B, 2A-2B, 3-4, 5A-5C, 6-12, 13A-13B, 14-15, 16A-16B, 17A-17B, 18A-18D, 19A-19D, 20A-20D, 21, 22A-22B, 23, 24A-24B, 25A-25B, 26A-26B, 27A-27C, 28-38, 39A-39C, 40, 41A-41B, 42A-42D, 43A-43B, 44A-44B, 45, and 46, corresponding to the informal drawings submitted with the above-captioned application. Identification of the drawings is provided in accordance with 37 C.F.R. § 1.84(c). Acknowledgment of the receipt, approval, and entry of these formal drawings into this application is respectfully requested.

It is not believed that an extension of time is required, other than any already provided herewith. However, if an extension of time is needed to prevent abandonment of the application, then such extension of time is hereby petitioned. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Date: April 30, 2002
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